RESEARCH PAPER

Formulation and Evaluation of a Polyherbal Vaginal Suppository for Vaginal Infections

Jyoti Krishnaji Gayakawad[1], Jayasheela M Goni[2*], Veena B Kupati[3], Santosh F Patil[4], Anil Kumar K M[5]

[1] PG Scholar, Department of PG Studies in Prasuti Tantra and Stree Roga, KAHER's Shri B.M.K. Ayurveda Mahavidyalaya & PG Research Centre, Belagavi, Karnataka, India - 590003.

[2*] Professor, Department of PG Studies in Prasuti Tantra and Stree Roga, KAHER's Shri B.M.K. Ayurveda Mahavidyalaya & PG Research Centre, Belagavi, Karnataka, India - 590003. Email: jay300662@gmai.com

[3] Associate Professor, Department of PG Studies in Rasa Shastra evum Bhaishajya Kalpana, KAHER's Shri B.M.K. Ayurveda Mahavidyalaya & PG Research Centre, Belagavi, Karnataka, India - 590003.

[4] Department of PG Studies in Agada Tantra, KAHER's Shri B.M.K. Ayurveda Mahavidyalaya & PG Research Centre, Belagavi, Karnataka, India - 590003.

[5] Department of Environmental Science, JSS Academy of Higher Education and Research, Mysuru - 570015, India.

ABSTRACT

Background

Vaginal infections are among the most prevalent gynaecological conditions affecting women of reproductive age, commonly caused by bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis. The vaginal route offers targeted drug delivery with improved local bioavailability. Traditional Ayurvedic formulations like Lodhradi Gana possess therapeutic potential but lack standardized dosage forms.

Objective

To formulate and evaluate a standardized polyherbal vaginal suppository using Lodhra (Symplocos racemosa), Palasha (Butea monosperma), Ashoka (Saraca asoca), Katphala (Myrica esculenta), and Sarja (Vateria indica) for potential management of vaginal infections.

Materials and Methods

A water-soluble solid extract (Ghana) was prepared via decoction and incorporated into suppositories using the fusion method with Suppocire® NAS 50 as the base. Four formulation trials (T1–T4) were designed with variations in excipients. The optimized formulation was evaluated for organoleptic properties, uniformity of weight, pH, hardness, melting time, disintegration time, microbial limit test, antimicrobial activity, and stability as per standard protocols.

Results

Among the four trials, T4 demonstrated optimal characteristics with good homogeneity and absence of phase separation. The optimized formulation showed acceptable physicochemical properties, including uniform weight (3.547 ± 0.085 g), pH (4.94 ± 0.01), and hardness (3.00 ± 0.03 kg/cm²). The suppositories melted and disintegrated within acceptable time limits. Microbial limit tests confirmed the absence of contamination. Antimicrobial evaluation revealed selective antifungal activity against Candida albicans (13 mm zone of inhibition), while no activity was observed against Staphylococcus aureus and Escherichia coli. Stability studies indicated no significant changes over 6 months at room temperature.

Conclusion

A stable and standardized polyherbal vaginal suppository was successfully developed. The formulation demonstrated suitable physicochemical characteristics and selective antifungal activity, indicating its potential in the management of fungal vaginal infections. Further studies are required to establish drug release, in vivo efficacy, and clinical applicability.

Keywords: Polyherbal formulation, Vaginal suppository, Lodhradi Gana, Candida albicans, Antifungal activity, Vaginal drug delivery, Ayurveda, Stability

How to cite this article: Gayakawad J K, Goni J M, Kupati V B, Patil S F, Anil Kumar K M. Formulation and Evaluation of a Polyherbal Vaginal Suppository for Vaginal Infections. Int J Drug Deliv Technol. 2026;16(37s): 818-825. DOI: 10.25258/ijddt.16.37s.105

Source of support: Nil.

Conflict of interest: None

Introduction:

Vaginal infections are the most common gynaecological problems affecting women of reproductive age, significantly impacting their quality of life (1). Bacterial vaginosis, vulvovaginal candidiasis, and trichomoniasis are the common causes of vaginal infections and are responsible for 40-50%, 20-25% and 15-20% of cases respectively (2). These conditions are characterised by inflammation of the vaginal mucosa, leading to symptoms such as abnormal discharge, pain, itching and burning sensation (3).

The vaginal route of drug delivery offers distinct advantages in the management of such conditions, including direct access to the site of infection, avoidance of first-pass metabolism, and improved local bioavailability (4). Among the various vaginal dosage forms, vaginal suppositories are widely utilized due to their ease of administration, favourable retention, and ability to achieve optimal localised therapeutic action.

The *Lodhradi Gana*, a group of 13 medicinal plants described in Ayurveda, is indicated for the management of gynaecological disorders, including vaginal infections. (5) However, their application is primarily in traditional forms, with comparatively limited emphasis on standardization and reproducibility. Advances in pharmaceutical technology provide a structured framework for developing traditional therapeutics into standardized dosage forms with improved stability, uniformity, and patient acceptability.

In the present study, a rational selection of *Lodhra* (*Symplocos racemosa* Roxb.), *Palasha* (*Butea monosperma* (Lam.) Kuntze), *Ashoka* (*Saraca asoca* Roxb.), *Katphala* (*Myrica esculenta* Buch-Ham.), and *Sarja* (*Vateria indica*) from *Lodhradi Gana* was undertaken based on classical references, therapeutic indication and suitability for formulation development. These drugs are known for their astringent, antimicrobial, and anti-inflammatory properties, (6-11) which support their use in vaginal infections.

Hence, the present study aims to formulate and evaluate a polyherbal vaginal suppository focusing on the development of a stable formulation suitable for local application.

Material and Methods –

Materials

Lodhra (Symplocos racemosa Roxb*), Palasha (Butea monosperma (*Lam*)* Kuntze*), Ashoka (Saraca asoca* Roxb*), Katphala (Myrica esculenta* Buch-Ham*)* and *Sarja (Vateria indica)* were used as active ingredients. All the raw drugs were procured from GMP certified KLE Pharmacy, Belagavi, Karnataka, India and authenticated from CRF-AYUSH approved drug testing laboratory for ASU drugs, Government of India, KAHER's Shri B M Kankanawadi Ayurveda Mahavidyalaya Belagavi. The raw drugs were subjected to standard organoleptic and physicochemical evaluation as per the API to ensure quality. The suppository base, Suppocire® NAS 50, was sourced from Gattefossé India Pvt. Ltd., Mumbai, Maharashtra, India. Tween 80 (Polysorbate 80) and distilled water were obtained from the institutional laboratory and used as excipients in the formulation.

Methodology

Development of *Lodhradi* Vaginal Suppository was carried out in four stages:

Preparation of *Lodhradi* Coarse powder (*Lodhradi Kashaya Churna)* (12):

Lodhra [Symplocos racemosa Roxb*], Palasha [Butea monosperma (*Lam*)* Kuntze*], Ashoka [Saraca asoca* Roxb*], Katphala [Myrica esculenta* Buch-Ham*]* and *Sarja [Vateria indica]* were taken in equal proportions and pulverised separately using a mechanical pulveriser. The powdered drugs were passed through 40-mesh sieve to ensure uniform particle size then mixed thoroughly to obtain a homogeneous coarse powder.

Preparation of *Lodhradi* Decoction (*Lodhradi Kashaya)* (13):

The coarse powder (1 part) is soaked in 16 parts of water for 16 hours. The mixture was then boiled over low flame with intermittent stirring until the volume was reduced to one-fourth of the initial quantity, and filtered to obtain the decoction.

Preparation of *Lodhradi Water Soluble Solid Extract (Lodhradi Ghana)* (14):

The prepared decoction was further heated over moderate flame with continuous stirring until complete evaporation of water, resulting in a semisolid extract.

Formulation of *Lodhradi* Vaginal Suppository:

The suppositories were prepared using the fusion method. Four formulation trials (T1–T4) were carried out using a fixed quantity of Lodhradi solid extract (500 mg) and suppository base (3 g), with variations in the use of distilled water and Tween 80. Tween 80 was incorporated as a surfactant to enhance dispersion of the extract, while distilled water was used to facilitate uniform mixing.

Table 1: Composition of Different Trials

Component	**Trial 1**	**Trial 2**	**Trial 3**	**Trial 4**
Drug (Lodhradi solid extract*)*	500 mg	500 mg	500 mg	500 mg
Base	3 g	3 g	3 g	3 g
Tween 80 (20%)	-	-	60 mg	60 mg
Distilled Water	-	1 mL	-	-

The suppository base was accurately weighed and melted on a water bath maintained at 50–60°C until a clear molten mass was obtained. The formulation components were then incorporated according to the respective trial design with continuous stirring to ensure uniform mixing.

- Trial 1 (T1): The extract was directly incorporated into the molten base and stirred until a homogeneous mixture was obtained.
- Trial 2 (T2): The extract was first dispersed in a small quantity of distilled water and then added to the molten base with continuous stirring.
- Trial 3 (T3): Tween 80 was melted along with the base, followed by the addition of the extract with constant stirring.
- Trial 4 (T4): The extract was triturated with the molten base and Tween 80 to form a smooth mixture, followed by remelting and thorough mixing to ensure uniformity.

The final molten mixtures were poured into pre-calibrated suppository moulds (3 g capacity) and allowed to solidify under refrigerated conditions at 4°C. The prepared suppositories were wrapped in butter paper and stored in airtight container until further evaluation.

Evaluation parameters:

- Organoleptic characteristics:

Four formulation trials (T1-T4) were evaluated for organoleptic characteristics including appearance, texture, colour, odour, homogeneity and absence of phase separation to select the optimized formulation for further evaluation.

- Uniformity of Weight (15):

The suppositories (n=20) were weighed individually using an analytical balance. The average weight was calculated. The percentage deviation of each suppository from the average weight was also calculated.

- pH Testing (15):

A suppository was melted in 100 mL of distilled water at 37 °C to obtain a uniform mixture. After cooling to room temperature, the pH was measured using a calibrated digital pH meter.

- Hardness (15):

Hardness was measured using a Monsanto hardness tester. The instrument was calibrated prior to use, and the hardness was expressed in kg/cm^2. (n=6)

- Melting Time of Suppositories (15):

The suppositories (n=6) were placed in a crucible and were kept over a water bath at 37 °C. The time when the suppository started melting and the time when they melted completely were recorded and the total time duration was taken as melting time.

- Disintegration Time (15):

The disintegration time was determined using a disintegration apparatus containing 1000 mL of distilled water and maintained at 37±0.5 °C. The time required for complete disintegration was recorded.

- Microbial limit test (16):

The Microbial limit test was performed as per the Indian Pharmacopoeia Commission guidelines for non-sterile products. The total aerobic microbial count (TAMC) and total yeast and mold count (TYMC) were determined by the plate count method using Soybean Casein Digest Agar and Sabouraud Dextrose Agar, respectively. The

presence of specified microorganisms (Escherichia coli, Staphylococcus aureus and Pseudomonas aeruginosa) was also evaluated using appropriate selective media. The results were expressed as CFU/g and as presence or absence of specified pathogens

- Antimicrobial study (17):

The antimicrobial activity of the formulation was evaluated by the agar well diffusion method against Staphylococcus aureus (ATCC 12598), Escherichia coli (ATCC 25922), Candida albicans (ATCC 2091). The inoculum was standardized to 0.5 McFarland turbidity and uniformly spread on blood agar plates. Wells of approximately 5 mm diameter were prepared, and 50 µL of the test solution (50 mg dissolved in 10 mL DMSO) was introduced into each well. The plates were incubated at 37 °C for 48–72 hours under anaerobic conditions, and the zone of inhibition was measured in millimeters.

- Stability study (18):

The stability study was carried out at room temperature (25 ± 2 °C) based on ICH guidelines. The samples were stored in airtight containers and evaluated at 0,3 and 6 months for physicochemical parameters and microbial quality. Accelerated stability studies at 40 ± 2 °C were not performed, as the formulation exhibited melting at elevated temperatures due to the lipid nature of the base.

Results:

Formulation trials and Organoleptic evaluation.

Table 2: Formulation trials

Trial	Appearance	Texture	Homogeneity	Phase separation
T1	Bullet-shaped, solid, uniform surface, light brownish	Gritty, slightly coarse	Poor	Complete separation
T2	Bullet-shaped, smooth, uniform surface, light brownish	Gritty	Partial	Partial separation
T3	Bullet-shaped, smooth, uniform surface, dark brown	Slightly gritty, non-homogenous	Non-uniform	Non-uniform mixing, minor separation
T4	Bullet-shaped, smooth, uniform surface, dark brown	Soft, non-gritty	Good	None

Image 1: Formulation trial 1 (T1)

Image 2: Formulation trial 2 (T2)

Image 3: Formulation trial 3 (T3)

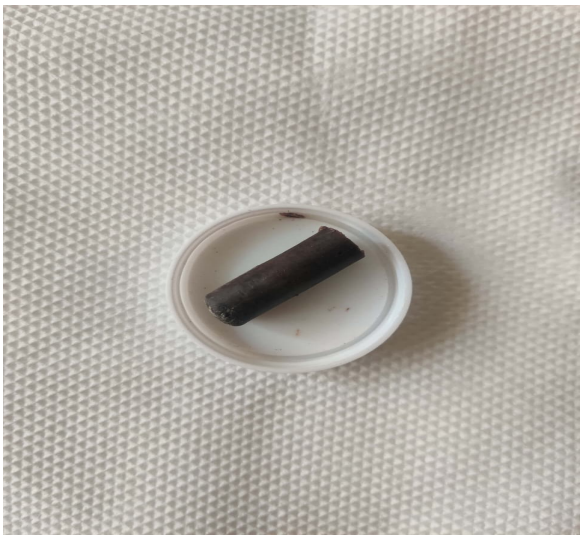

Image 4: Formulation trial (T4)

Based on these observations, Trial 4 was selected as optimized formulation for further evaluation.

Physicochemical evaluation of optimised formulation (T4):

- Uniformity of Weight:

Uniformity of weight was assessed for twenty suppositories. Individual weights ranged from 3.230g to 3.667g and the average weight of 3.547 ± 0085 g.

Table 3: Uniformity of weight

Suppository	Weight (g)	Deviation (%)
1	3.625	2.20
2	3.602	1.55
3	3.565	0.51
4	3.592	1.27
5	3.230	8.94
6	3.587	1.13
7	3.468	2.23
8	3.667	3.38
9	3.582	0.99
10	3.592	1.27
11	3.540	0.20
12	3.545	0.06
13	3.538	0.25
14	3.547	0
15	3.535	0.34
16	3.550	0.08
17	3.532	0.42
18	3.552	0.14
19	3.536	0.31
20	3.548	0.03

- pH Testing:

The pH was measured in triplicate. The values obtained were 4.94, 4.96, and 4.96, and the average pH was 4.94 ± 0.01.

- Hardness:

Suppository	Hardness (kg/cm^2)
1	2.95
2	3.00
3	3.05
4	2.98
5	3.02
6	3.00

Mean hardness 3.00 ± 0.03 kg/cm^2

- Melting Time of Suppositories:

The suppositories started melting after 10 minutes and melted completely within 2 hours.

- Disintegration time:

The disintegration time of suppositories ranged from 11minutes 30 seconds to 12 minutes 12 seconds, with a mean value of 11 min 54 sec ± 17 sec.

Suppository	Disintegration time (min)
1	11 min 30 sec
2	12 min 05 sec
3	11 min 48 sec
4	12 min 12 sec
5	11 min 42 sec

6	12 min 08 sec

- Microbial limit test:

Total microbial count		
	Limits (IP)	Results
TAMC (Total Aerobic Microbial Count)	30-300 cfu/g	No growth
TYMC (Total Yeast and Mold Count)	10-100 cfu/g	No growth
Test for specified microorganisms		
	Limits (IP)	Results
E. Coli	Absent / 100 g	Absent
S. aureus	Absent / 100 g	Absent
P. aeruginosa	Absent / 100 g	Absent

- Antimicrobial activity

The antimicrobial activity of the formulation was assessed based on the zone of inhibition.

Microorganism	ATCC strain	Type	Zone of inhibition(mm)
S aureus	ATCC 12598	Gram-positive bacterium	Resistant
E coli	ATCC 25922	Gram-negative bacterium	Resistant
Candida albicans	ATCC 2091	Yeast/fungal pathogen	13mm

Image 5: ZOI- *S. aureus*

Image 6: ZOI- *E. coli*

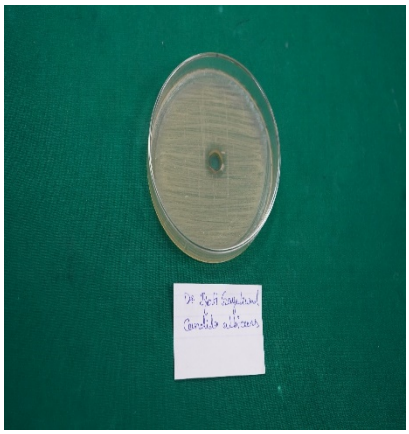

Image 7: ZOI- *C. albicans*

- Stability Study:

Organoleptic characteristics		
	After 3 months	After 6 months
Appearance	Bullet-shaped, smooth, uniform	Bullet-shaped, smooth, uniform
Texture	Soft and firm	Soft and firm
Colour	Dark brown	Dark brown
Odour	Characteristic	Characteristic
Physicochemical analysis		
	After 3 months	After 6 months
pH	4.96 ± 0.02	4.96 ± 0.06
Hardness	3.01 ± 0.03 kg/cm^2	3.04 ± 0.04 kg/cm^2
Melting time	Complete melting within 2 hours	Complete melting within 2 hours
Disintegration time	12min 34 sec ± 28 sec	12min 48 sec ± 12 sec
Microbial limit test		
Total microbial count		

	Limits (IP)	After 3 months	After 6 months
TAMC (Total Aerobic Microbial Count)	30-300 cfu/g	No growth	No growth
TYMC (Total Yeast and Mold Count)	10-100 cfu/g	No growth	No growth
Test for specified microorganisms			
	Limits (IP)	After 3 months	After 6 months
E. Coli	Absent / 100 g	Absent	Absent
S. aureus	Absent / 100 g	Absent	Absent
P. aeruginosa	Absent / 100 g	Absent	Absent

Discussion:

Among the four formulation trials (T1-T4), T4 exhibited optimal characteristics, which can be attributed to the combined use of Tween 80 and the trituration–remelting technique. The inclusion of a surfactant likely improved the wettability and dispersion of the hydrophilic herbal extract within the lipophilic base (Suppocire® NAS 50), thereby minimizing phase separation. In contrast, formulations lacking surfactant (T1 and T2) or with insufficient incorporation techniques (T3) showed poor homogeneity and instability. These observations are consistent with established formulation principles, where incompatibility between hydrophilic and lipophilic components necessitates the use of appropriate surfactants to ensure uniform drug distribution.

The optimized formulation demonstrated acceptable physicochemical properties. The average weight variation was within acceptable limits of IP standards. The pH (4.94 ± 0.01) was close to the physiological vaginal range, indicating suitability for local application without significant risk of irritation or disruption of normal vaginal flora. The hardness (3.00 ± 0.03 kg/cm²) indicated adequate mechanical strength for handling and storage. The melting and disintegration profiles suggest that the formulation is capable of softening and releasing the active constituents at body temperature. Microbial limit testing confirmed compliance with API standards, with no detectable microbial contamination or specified pathogens. The antimicrobial evaluation revealed selective antifungal activity against Candida albicans (13 mm zone of inhibition), while no activity was observed against Staphylococcus aureus and Escherichia coli. However, the absence of antibacterial activity suggests limited effectiveness in infections of bacterial origin. The stability study demonstrated that the formulation remained stable over 6 months at room temperature, with no significant changes in organoleptic, physicochemical, or microbial parameters. Minor variations observed in pH, hardness, and disintegration time were within acceptable limits. However, the absence of accelerated stability studies limits the prediction of long-term stability under stress conditions.

Overall, the study establishes the feasibility of developing a stable and standardized polyherbal vaginal suppository. Nevertheless, the lack of drug release studies, in vivo evaluation, and broader antimicrobial assessment represents key limitations that should be addressed in future research.

Conclusion:

A polyherbal vaginal suppository was successfully formulated and evaluated. The optimized formulation (T4) demonstrated satisfactory organoleptic properties, acceptable physicochemical characteristics, microbial quality and stability over a 6-month period. The formulation exhibited selective antifungal activity against *Candida albicans,* indicating its potential utility in the management of fungal vaginal infections. Further studies involving drug release profiling, in vivo evaluation, and clinical validation are necessary to establish its efficacy and clinical acceptability.

CONFLICT OF INTEREST:

The authors have no conflicts of interest regarding this study**.**

Acknowledgements:

The authors acknowledge Gattefossé India Pvt. Ltd., Mumbai, Maharashtra, India, for providing the suppository base (Suppocire® NAS 50) used in the study.

REFERENCES:

1. David W Denning, Matthew Kneale, Jack D Sobel, Riina Rautemaa-Richardson, Global burden of recurrent vulvovaginal candidiasis: a systematic review, The Lancet Infectious Diseases, Volume 18, Issue 11, 2018, Pages e339-e347, ISSN 1473-3099, DOI: https://doi.org/10.1016/S1473-3099(18)30103-8.
2. Paladine HL, Desai UA. Vaginitis: Diagnosis and Treatment. Am Fam Physician. 2018 Mar 1;97(5):321-329. PMID: 29671516.
3. Centers for Disease Control and Prevention. Diseases characterized by vulvovaginal itching, burning, irritation, odor, or discharge. In: Sexually transmitted infections treatment guidelines, 2021. Atlanta (GA): CDC; 2021 [cited 2026 Mar 24]. Available from: https://www.cdc.gov/mmwr/volumes/70/rr/rr7004a1.htm
4. M. Tamil Mani Subi, Nandhakumar Selvasudha, Hannah R. Vasanthi, Vaginal drug delivery system: A promising route of drug administration for local and systemic diseases, Drug Discovery Today, Volume 29, Issue 6, 2024, 104012, ISSN 1359-6446, https://doi.org/10.1016/j.drudis.2024.104012.
5. Kaviraj Ambikadutta Shastri. Susruta Samhita of Maharshi Susruta Part-I, Varanasi. Chaukhambha Sanskrit Sansthan. Sutrasthana Chapter-38: Page-184.
6. The Ayurvedic Pharmacopoeia of India. Part-I, Vol-I, Government of India Ministry of health and family welfare, Department of Ayush.
7. Dr. J. L. N. Sastry. Illustrated Dravyaguna vijnana – Study of the Essential Medicinal Plants in Ayurveda Vol-II, Varanasi. Chaukhambha Orientalia 2018. Page 78-86.
8. Dr. J. L. N. Sastry. Illustrated Dravyaguna vijnana – Study of the Essential Medicinal Plants in Ayurveda Vol-II, Varanasi. Chaukhambha Orientalia 2018. Page 144-148.
9. Dr. J. L. N. Sastry. Illustrated Dravyaguna vijnana – Study of the Essential Medicinal Plants in Ayurveda Vol-II, Varanasi. Chaukhambha Orientalia 2018. Page 192-195.
10. Dr. J. L. N. Sastry. Illustrated Dravyaguna vijnana – Study of the Essential Medicinal Plants in Ayurveda Vol-II, Varanasi. Chaukhambha Orientalia 2018. Page 828-831.
11. Dr. Prakash L. Hegde, Dr Harini A, A Textbook of Dravyaguna Vijnana Part-II, Varanasi. New Delhi. Chaukhambha publications 2010.
12. Sharangadhara, Sharangadhara Samhita, Deepika Hindi Commentary by Bramhanand Tripathi, Madyama Khanda, Varanasi: Chaukambha Surabharati Prakashana; Reprint 2010, p. 6/1-166-171.
13. Sharangadhara, Sharangadhara Samhita, Deepika Hindi Commentary by Bramhanand Tripathi, Madyama Khanda, Varanasi: Chaukambha Surabharati Prakashana; Reprint 2010, p. 2/1-127-133.
14. AcharyaSharangadara, edited by Shrikanthamurthy KR. Sharangadara Madhyama khanda. 7thedi. Varanasi: ChaukhambaOrientalia; 2007. p. 56-73.
15. Bassi A, Sharma G, Deol PK, Madempudi RS, Kaur IP. Preclinical Potential of Probiotic-Loaded Novel Gelatin-Oil Vaginal Suppositories: Efficacy, Stability, and Safety Studies. Gels. 2023 Mar 19;9(3):244. doi: 10.3390/gels9030244. PMID: 36975693; PMCID: PMC10048646.
16. Indian Pharmacopoeia Commission. Indian Pharmacopoeia 2022. Vol. I. Ghaziabad: Indian Pharmacopoeia Commission; 2022.
17. Schwalbe R, Steele-Moore L, Goodwin AC. Antimicrobial susceptibility testing protocols. Boca Raton: CRC Press; 2007.
18. International Council for Harmonisation. ICH Harmonised Guideline Q1A(R2): Stability Testing of New Drug Substances and Products. Geneva: ICH; 2003.